[86] Potter & Oxford (1979; *Br Med Bull* 35: 69-75.

[87] Halperin et al. (1979) *Am J Public Health* 69:1247-50.

[88] Herbert et al. (1979) *J Inject Dis* 140:234-8.

[89] Greenbaum et al. (2004) *Vaccine* 22:2566-77.

[90] Zurbriggen et al. (2003) *Expert Rev Vaccines* 2:295-304.

[91] Piascik (2003) *J Am Pharm Assoc* (Wash D.C.). 43:728-30.

[92] Mann et al. (2004) *Vaccine* 22:2425-9.

[93] Chen et al. (2003) *Vaccine* 21:2830-6.

What is claimed:

1. An influenza virus vaccine for raising an immune response in a patient of 6 to <36 months of age comprising: (i) hemagglutinin from at least two influenza A virus strains and at least two influenza B virus strains wherein the concentration of hemagglutinin per strain is at least 25 μg/mL; and (ii) an oil-in-water emulsion adjuvant with submicron oil droplets, comprising squalene, where the squalene concentration is ≤10 mg/mL and the minimum amount of squalene per dose is 0.5 mg, and wherein the influenza B virus strains include a B/Victoria/2/87-like influenza B virus strain and a B/Yamagata/16/88-like influenza B virus strain, and wherein the vaccine has a unit dose volume of 0.5 mL;

wherein the hemagglutinin is in the form of split virions, or purified surface antigens.

2. The vaccine of claim **1**, wherein the vaccine:

(a) comprises hemagglutinin from (i) a H1N1 influenza A virus strain; (ii) a H3N2 influenza A virus strain; (iii) a B/Victoria/2/87-like influenza B virus strain; and (iv) a B/Yamagata/16/88-like influenza B virus strain; and/or

(b) wherein the ratio of squalene to hemagglutinin in the vaccine is 42:1.

3. The vaccine of claim **1**, wherein the vaccine is:

(a) a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain, a squalene concentration of 9.75 mg/mL, and a unit dosage volume of 0.5 mL; or

(b) a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain, a squalene concentration of 4.88 mg/mL, and a unit dosage volume of 0.5 mL.

4. An influenza virus vaccine for raising an immune response in a patient of 6 to <36 months of age comprising: (i) hemagglutinin from at least two influenza A virus strains and at least two influenza B virus strains wherein the concentration of hemagglutinin per strain is at least 25 μg/mL; and (ii) an oil-in-water emulsion adjuvant with submicron oil droplets, comprising squalene, where the squalene concentration is ≤10 mg/mL and the amount of squalene per dose is 2.4 or 1.2 mg, and wherein the influenza B virus strains include a B/Victoria/2/87-like influenza B virus strain and a B/Yamagata/16/88-like influenza B virus strain, and wherein the vaccine has a unit dose volume of 0.2-0.3 mL.

5. The vaccine of claim **4**, wherein the hemagglutinin is in the form of split virions, or purified surface antigens.

6. The vaccine of claim **4**, wherein the vaccine has a unit dose volume of 0.25 mL.

7. The vaccine of claim **4**, wherein the vaccine is:

(a) a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain and a squalene concentration of 9.75 mg/mL; or

(b) a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain and a squalene concentration of 4.88 mg/mL.

8. An influenza virus vaccine for raising an immune response in a patient of 6 to <36 months of age comprising: (i) hemagglutinin from at least two influenza A virus strains and at least two influenza B virus strains wherein the concentration of hemagglutinin per strain is at least 25 μg/mL; and (ii) an oil-in-water emulsion adjuvant with submicron oil droplets, comprising squalene, where the amount of squalene per dose is 2.4 or 1.2 mg, and wherein the influenza B virus strains include a B/Victoria/2/87-like influenza B virus strain and a B/Yamagata/16/88-like influenza B virus strain, and wherein the vaccine has a unit dose volume of 0.25 mL.

9. The vaccine of claim **8**, wherein the hemagglutinin is in the form of split virions, or purified surface antigens.

10. The vaccine of claim **8**, wherein the vaccine is:

(a) a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain and a squalene concentration of 9.75 mg/mL; or

(b) a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain and a squalene concentration of 4.88 mg/mL.

11. The vaccine of claim **1**, wherein the vaccine is to be administered in more than one dose.

12. The vaccine of claim **4**, wherein the vaccine is to be administered in more than one dose.

13. The vaccine of claim **8**, wherein the vaccine is to be administered in more than one dose.

14. The vaccine of claim **1**, wherein the hemagglutinin is in the form of split virions.

15. The vaccine of claim **4**, wherein the hemagglutinin is in the form of split virions.

16. The vaccine of claim **8**, wherein the hemagglutinin is in the form of split virions.

17. The vaccine of claim **1**, wherein the hemagglutinin is in the form of purified surface antigens.

18. The vaccine of claim **4**, wherein the hemagglutinin is in the form of purified surface antigens.

19. The vaccine of claim **8**, wherein the hemagglutinin is in the form of purified surface antigens.

20. The vaccine of claim **1**, wherein the vaccine is a tetravalent inactivated influenza vaccine with a A/H1N1 strain, a A/H3N2 strain, an influenza B virus strain in the B/Yamagata lineage, and an influenza B virus strain in the B/Victoria lineage, having a hemagglutinin concentration of 30 μg/mL per strain, a squalene concentration of 9.75 mg/mL, and a unit dosage volume of 0.5 mL.

* * * * *